3,540,431 to Uddin. The Examiner has also rejected Claims 38-43 and 51-57 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,522,790 to Moll et al.

Claims 38 and 51 have been amended to recite that the device comprises an endothelialization membrane for promoting endothelialization across the tubular body structure.

As described in the specification, the presently claimed device inhibits the escape of thrombus or other materials (emboli) from the left atrial appendage. The device is disposed adjacent the opening of the left atrial appendage in a position which traverses the opening. Although the embolic containment membrane is porous, the pore size is such that it enables cell growth or other natural processes to create a smooth surface which may minimize turbulent flow or eddies of blood, while it functions to inhibit escape of embolic material.

Metais is directed to a filter device for preventing passage of embolisms which exceed the filter size, but which allows blood flow. Metais fails to disclose an endothelialization membrane for promoting endothelialization across the mouth of the left atrial appendage. Quite the opposite, the structure of Metais is intended to be used as a venous filter in which total occlusion would result in mortality or severe morbidity in the patient. Accordingly, Metais teaches the opposite of Applicants' structure by providing an amorphous-structure carbon coating on portions of the filter which are not in contact with the vessel wall. This limits endothelialization to the portions of the filter in contact with the vessel wall. See, for example, column 3 lines 51 through 66.

Accordingly, Applicants respectfully submit that Metais fails to disclose every element in Applicants' independent Claims 38 and 51. Claims 38 through 45 and Claims 51-100 are therefore believed to be novel over Metais.

Uddin is also directed to a vena cava filter device. The canopy portion of the device includes a plurality of holes. See Figure 4. Each of the holes 32 has a circular cross-section with a diameter "on the order of about 3 mm". Column 2 line 47. This is necessary in order to accommodate the return blood flow function of the vena cava.

Uddin thus fails to disclose an endothelialization membrane for promoting endothelialization across the opening to the left atrial appendage. Applicants believe that holes of 3 mm in diameter will not permit an occlusive endothelial lining to form. Uddin apparently believes so as well. See, for example, column 3 lines 43 through 46:

> The filter will permit certain passage of the blood flow to the heart to be pumped to the body including the lungs, and without the complete reliance being placed upon the collateral circulation.

See also column 3 line 50 through column 4 line 5:

> Additionally, an anticoagulant substance may be coated over the filter, and particularly on the upstream side face to resist adherence of clots to the filter and to discourage any tendency of the filter to cause clotting by reason of its presence in the vein. In addition, the patient may be treated with any other anticoagulant medicines injected into the body by suitable means.

Accordingly, Applicants respectfully submit that Uddin fails to disclose all of the elements of independent Claims 38 and 51. Each of Claims 38 through 45 and 51 through 100 is thus believed to be novel over Uddin.

Moll et al. is unrelated to the claimed subject matter. Moll et al. is directed to an inflatable or enlargeable retraction device which uses a mechanical maintainer. The maintainer, in its enlarged position, maintains the organ retracted by the main inflatable chamber in its retracted condition. Moll et al. does not teach or suggest an embolic occlusion member having an endothelialization support, as presently claimed.

Accordingly, none of the cited references teaches or suggests a device for inhibiting the escape of thrombus as presently claimed. Applicants' claimed structure enables the minimally invasive implantation of a device at the opening to the left atrial appendage, for inhibiting stroke due the escape of embolic material. The endothelialization membrane on Applicants' claimed device initially exists as a porous structure, but over time supports a continuous endothelial lining to help integrate the device into the heart. Thus, although the preamble to independent Claim 38 recites an occlusion device, and the preamble to Claim 51 recites an embolic occlusion device, both relate to the structure described above. None of the prior art applied in the outstanding Office Action is believed to disclose a structure as claimed herein.

Accordingly, Applicants respectfully maintain that Claims 38 and 51 are patentable over Metais, Uddin and Moll et al. As Claims 39-45 and 52-100 are dependent on independent Claims 38 and 51, Claims 39-45 and 52-100 are patentable for at least these reasons.

CONCLUSION

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. In light of these amendments and remarks, reconsideration and withdrawal of the outstanding rejections is respectfully requested.

Any claim amendments which are not specifically discussed in the above remarks are not made for patentability purposes, and/or do not narrow the claims, and it is believed that the claims would satisfy the statutory requirements for patentability without the entry of such amendments. Rather, these amendments have only been made to increase claim readability, to improve grammar, and to reduce the time and effort required of those in the art to clearly understand the scope of the claim language. Furthermore, any new claims presented above are simply additional specific statements of inventive concepts described in the application as originally filed.

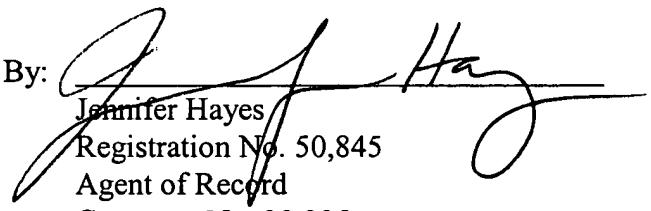
If the Examiner has any questions which may be answered by telephone, he is invited to call the undersigned directly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: October 11, 2002

By: 

Jennifer Hayes
Registration No. 50,845
Agent of Record
Customer No. 20,995
(619) 235-8550

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

38. (Amended) An occlusion device, for occluding a hollow body structure, comprising:

a proximal end, a distal end, and a longitudinal axis extending therethrough;

at least three supports extending between the proximal end and the distal end;

each support comprising an elongate, flexible element which is movable from a first orientation in which the element extends substantially parallel to the axis at no more than a first distance from the axis, to a second orientation in which at least a portion of the element is inclined with respect to the axis and is separated by at least a second distance from the axis which is greater than the first distance; and

an endothelialization membrane carried by the device, for promoting endothelialization across the hollow body structure.

51. (Amended) An embolic occlusion device, for implantation with in a tubular structure in the body, comprising:

[an occluding]a support member comprising at least three spokes which are movable from a reduced cross-section to an enlarged cross-section, the spokes movable from an axial orientation when the occluding member is in the reduced cross-section to an inclined orientation when the occluding member is in the enlarged cross-section, and

a porous endothelialization membrane carried by the support.

52. (Amended) An embolic occlusion device as in Claim 51, further comprising at least one hub on the support**[occlusion member]** for holding the spokes.

53. (Amended) An embolic occlusion device as in Claim 51, wherein the support**[occluding member]** comprises at least eight spokes.

54. (Amended) An embolic occlusion device as in Claim 52, wherein at least one spoke has a first end and a second end, and the first end is attached to the hub.

55. (Amended) An embolic occlusion device as in Claim 51, wherein each spoke comprises a proximal section, a distal section, and a bend in between the proximal and distal sections when the support**[occluding member]** is in the enlarged cross-section.

56. (Amended) An embolic occlusion device as in Claim 51, wherein the spokes comprise wire.

57 (Amended) An embolic occlusion device as in Claim 51, wherein the spokes are cut from a tube.

58. (Amended) An embolic occlusion device as in Claim 51, further comprising at least one tissue attachment element on the support**[occluding member]**.

59. (Amended) An embolic occlusion device as in Claim 58, wherein the tissue attachment structure comprises a tissue piercing element.

60. (Amended) An embolic occlusion device as in Claim 59, comprising at least one barb on each spoke.

S:\DOCS\JOH\JOH-2661.DOC/jt2
100902